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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,902	10/20/2004	Ruixiang Zhang	KI7043272001	5038
23639	7590	01/03/2006	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/511,902

Applicant(s)

ZHANG, RUIXIANG

Examiner

Susan D. Coe

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. The preliminary amendment filed October 20, 2004 has been received and entered.

Claims 1-6 are currently pending.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 2 is generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

In claim 2, line 3, "micro-strained" is indefinite because it is unclear what sizes are encompassed by "micro."

In claim 2, lines 3/4, the phrase "1 ml of concentrate corresponds to 0.5g of crude herb" is indefinite because it is not clear how to determine the correspondence between the concentrate and the crude herb. In addition, "crude" is indefinite because it is unclear what form the herb must be in in order to be considered "crude."

In claim 2, line 4, "decoting" appears to be a misspelling of "decocting." In addition, it is unclear what is "the concentrate decoting solution."

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In claim 2, line 10, the phrase “1 ml as corresponding to 4g of crude herb” is indefinite because it is not clear how to determine the correspondence between the water and the crude herb. In addition, “crude” is indefinite because it is unclear what form the herb must be in in order to be considered “crude.”

In claim 2, lines 10/11, it is unclear if the “-“ on line 10 is meant to indicate that the temperature of 8 degrees C is negative 8 degrees C.

In claim 2, line 11, the phrase “boiled for 15 minutes by adding 0.1 ~ 0.2% active carbon” is indefinite because it sounds like the active carbon causing the boiling to occur.

Lines 13, 14, and 18 are indefinite due to the use of parentheses. The use of parentheses is considered indefinite because it cannot be determined when the enclosed limitation is or is not to be included in the claim.

Line 14 is indefinite because the meaning of the phrase “sealed after filling” is unclear.

Line 15 is indefinite because the meaning of the phrase “of subsequently supporting agents” is unclear. “Subsequent” to what method step, and what are “supporting agents?”

Line 16 is indefinite because the phrase “by adding active carbon for injection” is unclear because it sounds like only the active carbon is injected.

Line 17 is indefinite because the meanings of “charged” and “pre-frozen” are unclear.

Line 18 is indefinite because “elevating temperature” is unclear. “Elevating” is not proper English and it is unclear what the temperature is “elevated” in comparison with.

3. Claim 3 is rendered indefinite due to the use of parentheses. The use of parentheses is considered indefinite because it cannot be determined when the enclosed limitation is or is not to be included in the claim.

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4. Claim 6 is indefinite because it is not clear what "supporting agents" are.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN 1346648 A (English translation) - May 1, 2002.

CN '648 teaches a composition for injection comprising *Ixeris Sonchifolia Hance* that contains both flavone and adenosine (see English translation, page 3, second paragraph). The injection is prepared by extracting the *I. sonchifolia* in water for an hour. The water extract is concentrated until each milliliter of extract equals 0.5 mg of the raw herb. The concentrate is cooled to less than 40 degrees C. A 10% calcium oxide suspension is added and the pH is adjusted to 10. The solution is centrifuged and the sediment is weighed. The sediment is suspended in 5.0 to 5.5 times of ethanol. Sulfuric acid is added and the pH is adjusted to 7.8 to 8.0. The solution is filtered with cardboard and the ethanol is evaporated. Water is added until one ml of the solution corresponds to 4g of raw herb. The solution is sterilized and then cooled to -5 degrees C for 24 hours. The solution is subjected to filtration and the pH is adjusted to 7.6 to 7.8 (see page 4). The reference also teaches that using active carbon in the extraction is known (see page 3, second paragraph).

The reference does not specifically teach all of the extraction parameters claimed by applicant. The pH, concentration and use of filtering are clearly result effective parameters that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal extraction conditions to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization extraction parameters would have been obvious at the time of applicant's invention. The reference also does not specifically teach the claimed ratios of flavone to adenosine. However, the reference does teach that these are active ingredients in the composition. Thus, a person of ordinary skill in the art would be motivated to optimize the ratio of these amounts in order to best achieve the results of the reference.

The reference also does not specifically teach using the stabilizers or "supporting" agents claimed by applicant. However, these ingredients are well known in the art to be appropriate and routine ingredients to add to pharmaceutical preparations. Therefore, it would be obvious to add these to the injection solution taught by the reference.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



12-21-05

Susan D. Coe  
Primary Examiner  
Art Unit 1655